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10/687,517	10/16/2003	Edgar Hommann	33628/US	5234
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David E. Bruhn		EXAMINER		
DORSEY & WHITNEY LLP		MEHTA, BHISMA		
Intellectual Property Department		ART UNIT		
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Minneapolis, MN 55402-1498		3767		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/687,517

Applicant(s)

HOMMANN ET AL.

Examiner

BHISMA MEHTA

Art Unit

3767

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8, 9, 12, 13, 17 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8, 9, 12, 13, 17 and 19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the releasing element projecting through an opening in the casing of the device where the dimensions of the opening limit movement of the releasing element must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. As to Applicant's remarks in lines 16-19 of page 5, Applicant is indicating that reference character 50 denotes the releasing element. However, in the specification, reference character has not been used for the releasing element. It is suggested that the objection to the drawing may be overcome by amending the specification to indicate that the releasing element is a radial projection (50).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an

application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claims 6, 9, 12, and 13 are objected to because of the following informalities: Claims 6 and 13 recite the limitation "said fluid product" in line 2. There is insufficient antecedent basis for this limitation in these claims. It is suggested that "said fluid product" be replaced with "the fluid product" as the fluid product has not been positively recited in line 1 of the claims. Appropriate correction is required. Applicant's arguments in line 21 of page 5 to line 2 of page 6 are not persuasive. The recitation of the fluid product is in the preamble of claim 6. This is considered to be a functional limitation and not a positive recitation of claimed subject matter.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 13, the language of "a sleeve arranged on one of the holder for the product container or the product container" is indefinite as there is no

Art Unit: 3767

positive recitation of the product container in the claim, and, therefore, it is unclear how the structural limitation of the sleeve being arranged on the product container can be achieved.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. Claims 1-5, 17, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacklich (U.S. Patent No. 4,444,560).

As to claim 1, Jacklich discloses an injection device for administering a fluid product having a casing (9), a piston rod (61) for dispensing the fluid product from a product container (37), and operating means for operating the piston rod. The operating means are provided laterally of a circumferential surface of the casing and have a lever with a lever arm (11) and a protrusion (57). The protrusion projects substantially perpendicular from the lever arm as seen in Figure 1 towards a longitudinal axis of the injection device and is fed into the casing. The operating means is pivotable in a radial direction relative to the casing about a fulcrum (shown at 51) and the protrusion is co-operable with the piston rod via a surface oblique relative to a longitudinal axis of the casing. Jacklich discloses that pivoting the lever arm of the operating means causes the protrusion to move along the oblique surface and displaces the piston rod. As seen in Figure 1, the fulcrum is provided on the circumferential surface in a generally central area of the injection device. The oblique surface is provided on the piston rod or can also be considered to be provided on the protrusion. At least a portion of the protrusion is connected to the piston rod by a T-connection such that the protrusion and the piston rod can slide relatively. As to claim 5, Jacklich discloses an indicator for indicating a product amount in the product container in the form of the ratchet teeth which are operated by pivoting the operating means (lines 40-44 of column 2).

As to claim 17, the injection device has a casing (9), operating means (11) are pivotable in a radial direction about a fulcrum (51) which is arranged laterally on the

injection device. The operating means also include a protrusion (65) which is co-operative with dispensing means (61) via a surface oblique relative to a longitudinal axis of the device. Pivoting of the operating means allows the dispensing means to be moved in an axial direction. The device also includes a releasing element (57) for releasing a dosage amount where the release element projects through an opening in the casing. The dimensions of the opening limit movement of the releasing element and the dosage amount is released by moving the releasing element from a first stopper on a first side of the opening to a second stopper on a second side of the opening opposite the first side (Figures 2 and 3). As to claim 19, the sleeve (21) is considered to be capable of surrounding the injection needle and being shiftable.

7. Claims 6, 9, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Brunel (U.S. Patent No. 6,575,939). Brunel discloses an injection device having a casing (10), dispensing means (6), and operating means (7). The injection device also includes a dosing means with a releasing element (15) which projects radially through an opening in the casing and an indicator for indicating a product amount (lines 11-14 of column 9). The releasing element is moved from a first stopper on a first side of the opening to a second stopper on a second side of the opening which is opposite to the first side as seen in Figures 14 and 15. The dimensions of the opening limit the movement of the releasing element, thereby setting the predetermined amount of the dosage and the indicator counts down by a dosage unit when the releasing element is moved (lines 34-39 of column 5 and lines 11-14 of column 9). As to claim 12, a guiding

means (26) is provided which is capable of guiding a needle cap to exchange the injection needle of the device.

8. Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Hommann et al (U.S. Patent Application Publication No. 2003/0144632). Hommann et al disclose an injection device having a casing (12), a holder (14) for a product container, an injection needle (16), and a needle protector. The needle protector comprises a sleeve (20) which is arranged on the holder such that the sleeve is shiftable in a longitudinal axis with respect to the holder to generally surround the injection needle in an advanced position. The holder and the sleeve are insertable into the casing and removable from the casing to exchange the product container. The sleeve serves as a guide for a needle cap used to exchange the needle.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jacklich in view of Cosmai (U.S. Patent No. 4,850,967). Jacklich discloses the device substantially as claimed. Even though Jacklich discloses administering the fluid product in doses and providing an indicator for indicating a product amount, Jacklich is silent on the injector comprising a scale up to a total number of dosages amounts present and counts down by one unit on the scale when the dispensing means or operating means is operated. Cosmai discloses an injection device having an indicator which comprises a scale (i.e. the markings) and counts down by a dosage unit when the dispensing means are operated. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the indicator of Jacklich with a scale as taught by Cosmai as both Jacklich and Cosmai disclose devices for administering a fluid in doses and Cosmai teaches that it is well known to provide a scales so that the number of dose being administered may be monitored.

Response to Arguments

11. Applicant's arguments filed December 13 2007 have been fully considered but they are not persuasive.

As to Applicant's arguments in line 8 of page 6 to line 6 of page 7, Jacklich does show operating means for operating the piston rod where the operating means are provided laterally of a circumferential surface of the casing and have a lever with a lever arm (11) and a protrusion (57). The protrusion (57) does project substantially

perpendicular from the lever arm (11) as seen in Figure 1 towards a longitudinal axis of the injection device.

As to Applicant's arguments in line 7 of page 7 to line 2 of page 8, Jacklich does disclose releasing the dosage amount by moving the releasing element from a first stopper on a first side of the opening to a second stopper on a second side of the opening opposite the first side as seen in Figure 2. The releasing element is moved from the first stopper of the first side of the opening (as shown in Figure 2) to a second stopper on a second side of the opening. The first stopper and the second stopper are located on the dispensing means (61) and are considered to be on a first side of the opening and a second side of the opening, respectively.

As to Applicant's arguments in line 3 of page 8 to line 7 of page 9, the releasing element (15) of Brunel is radially projecting through the opening in the casing Figure 2) and the dimensions of the opening does limit the movement of the releasing element such that a predetermined amount of the dosage is released (lines 34-39 of column 5 and lines 11-14 of column 9). In response to applicant's argument that Brunel does not disclose dosing means comprising a releasing element where the releasing element projects radially through an opening in the casing and dimensions of the opening limit movement of the releasing element to set the predetermined amount of the dosage, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

As to Applicant's arguments in lines 8-29 of page 9, Hommann does disclose a holder (14) for a product container as the holder is capable of holding a product container. The product container in claim 13 is not positively recited. The holder (14) is insertable into and removable from the casing (12). In response to applicant's argument that Hommann does not disclose a holder which is insertable into the casing and removable from the casing to exchange a product container, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bhisma Mehta/
Examiner, Art Unit 3767
/Kevin C. Simons/
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